April 3, 2013

This Report CONTAINS Confidential Business Information

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CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam:

( ) (formerly .) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns , an experimental aryl hydrazide insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is .

recently learned of new toxicological effects in a one month oral toxicity study of in rats. An outline of the study follows:

One month oral toxicity study of in rats

was administered daily in feed to male and female rats at dose levels of 10, 100, 300, and 1000 ppm for one month. The No Observed Adverse Effect Level (NOAEL) was 10 ppm for both sexes (male rats: 1.1 mg/kg/day, female rats: 1.0 mg/kg/day). In addition, severely dysfunctional pathological changes, such as atrophy of prostate, seminal vesicle, vagina (epithelium), uterus, and thymus were observed.

believes that the NOAEL of <200 mg/kg/day in an oral study of ≤ 4 weeks, and the pathological changes are reportable under TSCA 8(e).

Performing Laboratory:

Study methods:
Test substance:
Animals: BrlHan:WIST@Jcl(GALAS) rats, males and females, 6 animals/sex/group
Animal age at initiation of treatment: 5 weeks old
Body weight range at initiation of treatment: males: 107 to 118 g; females; 90 to 107 g
Administration route: Oral via diet
Dose levels: 10, 100, 300, and 1000 ppm
Treatment period: one month
Observation items: Clinical signs, body weight, food consumption, ophthalmology, urinalysis, motor activity, FOB, hematology, blood biochemistry, gross pathology, organ weight, histopathology, electron microscopic examination

RESULTS:
Low body weight and/or suppressed food consumption were observed in both male and female rats at 300 and 1000 ppm. As a result of hematology, blood biochemistry, gross pathology, organ weight or histopathology, some changes indicating hemolytic anemia were observed in both sexes at 100 ppm and above, and the effects on liver were observed in both sexes at 300 and 1000 ppm.

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm 's efforts to commercialize this compound. Please refer to the attached letter regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( ).

Sincerely,